



Patent  
Attorney's Docket No. 028722-317

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Pere Santamaria

Application No.: 10/005,917

Filed: December 7, 2001

For: COMPOSITIONS AND METHODS USEFUL IN  
AVIDITY THERAPY

) Group Art Unit: 1633

) Examiner: Unassigned

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**INFORMATION DISCLOSURE STATEMENT  
TRANSMITTAL LETTER**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Enclosed is an Information Disclosure Statement and accompanying form PTO-1449 for the above-identified patent application.

- No additional fee for submission of an IDS is required.
- The fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) is also enclosed.
- A certification under 37 C.F.R. § 1.97(e) is also enclosed.
- A certification under 37 C.F.R. § 1.97(e), and the fee of \$180.00 (126) as set forth in 37 C.F.R. § 1.17(p) are also enclosed.
- Charge \$\_\_\_\_\_ to Deposit Account No. 02-4800 for the fee due.
- A check in the amount of \$\_\_\_\_\_ is enclosed for the fee due.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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Alexandria, Virginia 22313-1404  
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By:

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Date: April 15, 2002



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Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. §1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed.

1. Amrani et al. 2001. Expansion of the antigenic repertoire of a single T cell receptor upon T cell activation. *J. Immunol.* 167(2):655-66.
2. Amrani, A., J. Verdaguer, P. Serra, S. Tafuro, R. Tan, and P. Santamaria. 2000. Progression of autoimmune diabetes driven by avidity maturation of a T-cell population. *Nature*. 406:739.
3. Amrani, A., J. Verdaguer, B. Anderson, T. Utsugi, S. Bou, and P. Santamaria. 1999. Perforin-independent beta cell destruction by diabetogenic CD8<sup>+</sup> T lymphocytes in transgenic nonobese diabetic mice. *J. Clin. Invest.* 103:1201.

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Page 2

4. Anderson, B., B.-J. Park, J. Verdaguer, A. Amrani, and P. Santamaria. 1999. Dominant CD8<sup>+</sup> T-cell response against a single peptide/MHC complex in autoimmune diabetes. *Proc. Natl. Acad. Sci. USA* 96:9311.
5. Bendelac, A., C. Carnaud, C. Boitard, and J. F. Bach. 1987. Syngeneic transfer of autoimmune diabetes from diabetic NOD mice to healthy neonates. *J. Exp. Med.* 166:823.
6. Bradley, B., K. Haskins, F. L. Rosa, and K. Lafferty. 1992. CD8 T cells are not required for islet destruction induced by a CD4<sup>+</sup> islet-specific T-cell clone. *Diabetes* 41:1603.
7. Christianson, S., L. Shultz, and E. Leiter. 1993. Adoptive transfer of diabetes into immunodeficient NOD-scid/scid mice. Relative contributions of CD4<sup>+</sup> and CD8<sup>+</sup> T-cells from diabetic versus prediabetic NOD.NON-thy-1a donors. *Diabetes* 42:44.
8. Daniel, D., R. Gill, N. Schloot, and D. Wegmann. 1995. Epitope specificity, cytokine production profile and diabetogenic activity of insulin-specific T cell clones isolated from NOD mice. *Eur. J. Immunol.* 25:1056.
9. Delovitch, T., and B. Singh. 1997. The nonobese diabetic mouse as a model of autoimmune diabetes: immune disregulation gets the NOD. *Immunity* 7:727.
10. DiLorenzo, T., T. Graser, T. Ono, G. Christianson, H. Chapman, D. Roopenian, S. Nathenson, and D. Serreze. 1998. MHC class I-restricted T-cells are required for all but end stages of diabetes development and utilize a prevalent T cell receptor  $\alpha$  chain gene rearrangement. *Proc. Natl. Acad. Sci. USA* 95:12538.
11. Haskins, K., and M. McDuffie. 1990. Acceleration of diabetes in young NOD mice with a CD4<sup>+</sup> islet-specific T cell clone. *Science* 249:1433.
12. Hayakawa, M., K. Yokono, M. Nagata, N. Hatamori, W. Ogawa, A. Miki, H. Mizoguti, and S. Baba. 1991. Morphological analysis of selective destruction of pancreatic beta cells by cytotoxic T lymphocytes in NOD mice. *Diabetes* 40:1210.
13. Hutchings, P., H. Rosen, L. O'Reilly, E. Simpson, S. Gordon, and A. Cooke. 1990. Transfer of diabetes in mice prevented by blockade of adhesion-promoting receptor on macrophages. *Nature* 348:639.

Information Disclosure Statement  
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Attorney's Docket No. 028722-317  
Page 3

- 14. Jun, H.-S., P. Santamaria, H.-W. Lim, M. Zhang, and J.-W. Yoon. 1999. Absolute requirement of macrophages for the development and activation of B-Cell cytotoxic CD8<sup>+</sup> T-Cells in T-Cell receptor transgenic NOD mice. *Diabetes* 48:34.
- 15. Jun, H., C. Yoon, L. Zbytnuik, N. v. Rooijen, and J. Yoon. 1999. The role of macrophages in T cell-mediated autoimmune diabetes in nonobese diabetic mice. *J. Exp. Med.* 189:347.
- 16. Kagi, D., B. Odermatt, P. Seiler, R. Zinkernagel, T. Mak, and H. Hengartner. 1997. Reduced incidence and delayed onset of diabetes in perforin-deficient nonobese diabetic mice. *J. Exp. Med.* 186:989.
- 17. Katz, J., C. Benoist, and D. Mathis. 1995. T helper cell subsets in insulin-dependent diabetes. *Science* 268:1185.
- 18. Katz, J., C. Benoist, and D. Mathis. 1993. Major histocompatibility complex class I molecules are required for the generation of insulitis in non-obese diabetic mice. *Eur. J. Immunol.* 23:3358.
- 19. Kay, T., J. Parker, L. Stephens, H. Thomas, and J. Allison. 1996. RIP-b2-microglobulin transgene expression restores insulitis, but not diabetes, in b2-microglobulinnull nonobese diabetic mice. *J. Immunol.* 157:3688.
- 20. Lo, D., C. Reilly, B. Scott, R. Liblau, H. McDevitt, and L. Burkly. 1993. Antigen-presenting cells in adoptively transferred and spontaneous autoimmune diabetes. *Eur. J. Immunol.* 23:1693.
- 21. McInerney, M., S. Rath, and C. Janeway. 1991. Exclusive expression of MHC class II proteins on CD45<sup>+</sup> cells in pancreatic islets of NOD mice. *Diabetes* 40:648.
- 22. Miller, B. J., M. C. Appel, J. J. O'Neil, and L. S. Wicker. 1988. Both the Lyt-2<sup>+</sup> and L3T4<sup>+</sup> T cell subsets are required for the transfer of diabetes in non-obese diabetic mice. *J. Immunol.* 140:52.
- 23. Nagata, M., P. Santamaria, T. Kawamura, T. Utsugi, and J.-W. Yoon. 1994. Evidence for the role of CD8<sup>+</sup> cytotoxic T cells in the destruction of pancreatic beta cells in NOD mice" *J. Immunology* 152:2042

Information Disclosure Statement  
Application No. 10/005,917  
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Page 4

- 24. Nagata, M., and J.-W. Yoon. 1992. Studies on autoimmunity for T cell-mediated beta cell destruction: distinct difference in the destruction of beta cells between CD4<sup>+</sup> and CD8<sup>+</sup> T cell clones derived from lymphocytes infiltrating the islets of NOD mice. *Diabetes* 41:998.
- 25. Nakano, N., H. Kikutani, H. Nishimoto, and T. Kishimoto. 1991. T cell receptor V gene usage of islet beta cell-reactive T cells is not restricted in non-obese diabetic mice. *J. Exp. Med.* 173:1091.
- 26. Peterson, J., and K. Haskins. 1996. Transfer of diabetes in the NOD-scid mouse by CD4 T cell clones. Differential requirement for CD8 T cells. *Diabetes* 45:328.
- 27. Santamaria, P., T. Utsugi, B. Park, N. Averill, S. Kawazu, and J. Yoon. 1995. Beta cell cytotoxic CD8<sup>+</sup> T cells from non-obese diabetic mice use highly homologous T cell receptor alpha chain CDR3 sequences. *J. Immunol.* 154:2494.
- 28. Schmidt, D., J. Verdaguer, N. Averill, and P. Santamaria. 1997. A mechanism for the major histocompatibility complex-linked resistance to autoimmunity. *J. Exp. Med.* 186:1059.
- 29. Serreze, D., and E. Leiter. 1994. Genetic and pathogenic basis of autoimmune diabetes in NOD mice. *Curr. Opin. Immunol.* 6:900.
- 30. Serreze, D., E. Leiter, G. Christianson, D. Greiner, and D. Roopenian. 1994. Major histocompatibility complex class I-deficient NOD.b1m<sup>null</sup> mice are diabetes and insulitis resistant. *Diabetes* 43:505.
- 31. Serreze, D., H. Chapman, D. Varnum, I. Gerling, E. Leiter, and L. Shultz. 1997. Initiation of autoimmune diabetes in NOD/Lt mice is MHC class I-dependent. *J. Immunol.* 157:3978.
- 32. Shimizu, J., O. Kanagawa, and E. Unanue. 1993. Presentation of beta cell antigens to CD4<sup>+</sup> and CD8<sup>+</sup> T cells of non-obese diabetic mice. *J. Immunol.* 151:1723.
- 33. Thivolet, C., A. Bendelac, P. Bedossa, J. F. Bach, and C. Carnaud. 1991. CD8<sup>+</sup> T cell homing to the pancreas in the nonobese diabetic mouse is CD4<sup>+</sup> T cell-dependent. *J. Immunol.* 146:85.

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Page 5

34. Tisch, R., and H. McDevitt. 1996. Insulin-dependent diabetes mellitus. *Cell* 85:291.
35. Utsugi, T., J.-W. Yoon, B.-J. Park, M. Imamura, N. Averill, S. Kawazu, and P. Santamaria. 1996. MHC class I-restricted infiltration and destruction of pancreatic islets by NOD mouse-derived beta cell-cytotoxic CD8<sup>+</sup> T-cell clones in vivo. *Diabetes* 45:1121.
36. Verdaguer, J., J.-W. Yoon, B. Anderson, N. Averill, T. Utsugi, B.-J. Park, and P. Santamaria. 1996. Acceleration of spontaneous diabetes in TCR $\beta$ -transgenic nonobese diabetic mice by beta cell-cytotoxic CD8<sup>+</sup> T cells expressing identical endogenous TCRA chains. *J. Immunol.* 157:4726.
37. Verdaguer, J., D. Schmidt, A. Amrani, B. Anderson, N. Averill, and P. Santamaria. 1997. Spontaneous autoimmune diabetes in monoclonal T cell nonobese diabetic mice. *J. Exp. Med.* 186:1663.
38. Vyse, T., and J. Todd. 1996. Genetic analysis of autoimmune disease. *Cell* 85:311.
39. Wang, B., A. Gonzalez, C. Benoist, and D. Mathis. 1996. The role of CD8<sup>+</sup> T-cells in initiation of insulin-dependent diabetes mellitus. *Eur. J. Immunol.* 26:1762.
40. Wicker, L., E. Leiter, J. Todd, R. Renjilian, E. Peterson, P. Fischer, P. Podolin, M. Zijlstra, R. Jaenisch, and L. Peterson. 1994. b2-microglobulin-deficient NOD mice do not develop insulitis or diabetes. *Diabetes* 43:500.
41. Wong, F., I. Visintin, L. Wen, R. Flavell, and J. CA Janeway. 1996. CD8 T cell clones from young NOD islets can transfer rapid onset of diabetes in NOD mice in the absence of CD4 T cells. *J. Exp. Med.* 183:67.
42. Wong, S., et. al. 1999. Identification of an MHC class I-restricted autoantigen in type 1 diabetes by screening an organ-specific cDNA library. *Nature Med.* 5:1026.
43. Yagi, H., M. Matsumoto, K. Kunimoto, J. Kawaguchi, S. Makino, and M. Harada. 1992. Analysis of the roles of CD4<sup>+</sup> and CD8<sup>+</sup> T cells in autoimmune diabetes of NOD mice using transfer to NOD athymic nude mice. *Eur. J. Immunol.* 22:2387.

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Page 6

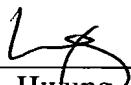
These documents are being submitted before a first Office Action on the merits, therefore no fee is required under 37 C.F.R. § 1.97(b). In the event an Office Action is mailed by the United States Patent and Trademark Office prior to receipt of this Information Disclosure Statement, the Commissioner is authorized to debit Deposit Account 02-4800 for the fee required by 37 C.F.R. §1.17(p).

By citing the above references, Applicants do not acquiesce or admit that any of these documents are "prior art" under 35 U.S.C. Applicants specifically reserve the right, where appropriate, to antedate any of the cited documents by an appropriate showing under 37 C.F.R. §1.131, §1.604, §1.608 or any other suitable means.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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Alexandria, Virginia 22313-1404

Date: April 15, 2002

APR 16 2002

SHEET 1 OF 3

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

ATTORNEY'S DKT NO.

028722-317

APPLICATION NO.

10/005,917

APPLICANT

Pere Santamaria

FILING DATE

December 7, 2001

GROUP

1633

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**U.S. PATENT DOCUMENTS**

Examiner Initials	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication (MM-DD-YYYY)
	Number	Kind Code (if known)		

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Foreign Patent Document		Country	Date of Publication (MM-DD-YYYY)	Translation	
	Number	Kind Code (if known)			Yes	No

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				
	Amrani et al. 2001. Expansion of the antigenic repertoire of a single T cell receptor upon T cell activation. <i>J. Immunol.</i> 167(2):655-66.				
	Amrani, A., J. Verdaguer, P. Serra, S. Tafuro, R. Tan, and P. Santamaria. 2000. Progression of autoimmune diabetes driven by avidity maturation of a T-cell population. <i>Nature</i> . 406:739.				
	Amrani, A., J. Verdaguer, B. Anderson, T. Utsugi, S. Bou, and P. Santamaria. 1999. Perforin-independent beta cell destruction by diabetogenic CD8 <sup>+</sup> T lymphocytes in transgenic nonobese diabetic mice. <i>J. Clin. Invest.</i> 103:1201.				
	Anderson, B., B.-J. Park, J. Verdaguer, A. Amrani, and P. Santamaria. 1999. Dominant CD8 <sup>+</sup> T-cell response against a single peptide/MHC complex in autoimmune diabetes. <i>Proc. Natl. Acad. Sci. USA</i> 96:9311.				
	Bendelac, A., C. Carnaud, C. Boitard, and J. F. Bach. 1987. Syngeneic transfer of autoimmune diabetes from diabetic NOD mice to healthy neonates. <i>J. Exp. Med.</i> 166:823.				
	Bradley, B., K. Haskins, F. L. Rosa, and K. Lafferty. 1992. CD8 T cells are not required for islet destruction induced by a CD4 <sup>+</sup> islet-specific T-cell clone. <i>Diabetes</i> 41:1603.				
	Christianson, S., L. Shultz, and E. Leiter. 1993. Adoptive transfer of diabetes into immunodeficient NOD-scid/scid mice. Relative contributions of CD4 <sup>+</sup> and CD8 <sup>+</sup> T-cells from diabetic versus prediabetic NOD.NON-thy-1a donors. <i>Diabetes</i> 42:44.				
	Daniel, D., R. Gill, N. Schlroot, and D. Wegmann. 1995. Epitope specificity, cytokine production profile and diabetogenic activity of insulin-specific T cell clones isolated from NOD mice. <i>Eur. J. Immunol.</i> 25:1056.				
	Delovitch, T., and B. Singh. 1997. The nonobese diabetic mouse as a model of autoimmune diabetes: immune disregulation gets the NOD. <i>Immunity</i> 7:727.				
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	Hayakawa, M., K. Yokono, M. Nagata, N. Hatamori, W. Ogawa, A. Miki, H. Mizoguti, and S. Baba. 1991. Morphological analysis of selective destruction of pancreatic beta cells by cytotoxic T lymphocytes in NOD mice. <i>Diabetes</i> 40:1210.				
	Hutchings, P., H. Rosen, L. O'Reilly, E. Simpson, S. Gordon, and A. Cooke. 1990. Transfer of diabetes in mice prevented by blockade of adhesion-promoting receptor on macrophages. <i>Nature</i> 348:639.				
	Jun, H.-S., P. Santamaria, H.-W. Lim, M. Zhang, and J.-W. Yoon. 1999. Absolute requirement of macrophages for the development and activation of B-Cell cytotoxic CD8 <sup>+</sup> T-Cells in T-Cell receptor transgenic NOD mice. <i>Diabetes</i> 48:34.				
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	Kagi, D., B. Odermatt, P. Seiler, R. Zinkernagel, T. Mak, and H. Hengartner. 1997. Reduced incidence and delayed onset of diabetes in perforin-deficient nonobese diabetic mice. <i>J. Exp. Med.</i> 186:989.				
Examiner Signature		Date Considered			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

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SHEET 2 OF 3

Substitute for form 1449A/PTO

ATTORNEY'S DKT NO.

C 28722-317

APPLICATION NO.

10/005,917

APPLICANT

Pere Santamaria

FILING DATE

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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## U.S. PATENT DOCUMENTS

Examiner Initials	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication (MM-DD-YYYY)
	Number	Kind Code (if known)		

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Foreign Patent Document		Country	Date of Publication (MM-DD-YYYY)	Translation <input type="checkbox"/> Yes <input type="checkbox"/> no
	Number	Kind Code (if known)			

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				
	Katz, J., C. Benoist, and D. Mathis. 1995. T helper cell subsets in insulin-dependent diabetes. <i>Science</i> 268:1185.				
	Katz, J., C. Benoist, and D. Mathis. 1993. Major histocompatibility complex class I molecules are required for the generation of insulitis in non-obese diabetic mice. <i>Eur. J. Immunol.</i> 23:3358.				
	Kay, T., J. Parker, L. Stephens, H. Thomas, and J. Allison. 1996. RIP-b2-microglobulin transgene expression restores insulitis, but not diabetes, in b2-microglobulin null nonobese diabetic mice. <i>J. Immunol.</i> 157:3688.				
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	McInerney, M., S. Rath, and C. Janeway. 1991. Exclusive expression of MHC class II proteins on CD45 <sup>+</sup> cells in pancreatic islets of NOD mice. <i>Diabetes</i> 40:648.				
	Miller, B. J., M. C. Appel, J. J. O'Neil, and L. S. Wicker. 1988. Both the Lyt-2 <sup>+</sup> and L3T4 <sup>+</sup> T cell subsets are required for the transfer of diabetes in non-obese diabetic mice. <i>J. Immunol.</i> 140:52.				
	Nagata, M., P. Santamaria, T. Kawamura, T. Utsugi, and J.-W. Yoon. 1994. Evidence for the role of CD8 <sup>+</sup> cytotoxic T cells in the destruction of pancreatic beta cells in NOD mice. <i>J. Immunology</i> 152:2042.				
	Nagata, M., and J.-W. Yoon. 1992. Studies on autoimmunity for T cell-mediated beta cell destruction: distinct difference in the destruction of beta cells between CD4 <sup>+</sup> and CD8 <sup>+</sup> T cell clones derived from lymphocytes infiltrating the islets of NOD mice. <i>Diabetes</i> 41:998.				
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	Peterson, J., and K. Haskins. 1996. Transfer of diabetes in the NOD-scid mouse by CD4 T cell clones. Differential requirement for CD8 T cells. <i>Diabetes</i> 45:328.				
	Santamaria, P., T. Utsugi, B. Park, N. Averill, S. Kawazu, and J. Yoon. 1995. Beta cell cytotoxic CD8 <sup>+</sup> T cells from non-obese diabetic mice use highly homologous T cell receptor alpha chain CDR3 sequences. <i>J. Immunol.</i> 154:2494.				
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	Serreze, D., and E. Leiter. 1994. Genetic and pathogenic basis of autoimmune diabetes in NOD mice. <i>Curr. Opin. Immunol.</i> 6:900.				
	Serreze, D., E. Leiter, G. Christianson, D. Greiner, and D. Roopenian. 1994. Major histocompatibility complex class I-deficient NOD.b1mnnull mice are diabetes and insulitis resistant. <i>Diabetes</i> 43:505.				
	Serreze, D., H. Chapman, D. Varnum, I. Gerling, E. Leiter, and L. Shultz. 1997. Initiation of autoimmune diabetes in NOD/Lt mice is MHC class I-dependent. <i>J. Immunol.</i> 157:3978.				
	Shimizu, J., O. Kanagawa, and E. Unanue. 1993. Presentation of beta cell antigens to CD4 <sup>+</sup> and CD8 <sup>+</sup> T cells of non-obese diabetic mice. <i>J. Immunol.</i> 151:1723.				
	Thivolet, C., A. Bendelac, P. Bedossa, J. F. Bach, and C. Carnaud. 1991. CD8 <sup>+</sup> T cell homing to the pancreas in the nonobese diabetic mouse is CD4 <sup>+</sup> T cell-dependent. <i>J. Immunol.</i> 146:85.				
	Tisch, R., and H. McDevitt. 1996. Insulin-dependent diabetes mellitus. <i>Cell</i> 85:291.				
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SHEET 3 OF 3

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STATEMENT BY APPLICANT**

ATTORNEY'S DKT No.  
028722-317APPLICATION NO.  
10/005,917APPLICANT  
Pere SantamariaFILING DATE  
December 7, 2001GROUP  
1633RECEIVE  
APR 1  
2002  
TECH CENTER  
1600/290

**U.S. PATENT DOCUMENTS**

Examiner Initials	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication (MM-DD-YYYY)
	Number	Kind Code (if known)		

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	Utsugi, T., J.-W. Yoon, B.-J. Park, M. Imamura, N. Averill, S. Kawazu, and P. Santamaria. 1996. MHC class I-restricted infiltration and destruction of pancreatic islets by NOD mouse-derived beta cell-cytotoxic CD8 <sup>+</sup> T-cell clones in vivo. <i>Diabetes</i> 45:1121.				
	Verdaguer, J., J.-W. Yoon, B. Anderson, N. Averill, T. Utsugi, B.-J. Park, and P. Santamaria. 1996. Acceleration of spontaneous diabetes in TCRb-transgenic nonobese diabetic mice by beta cell-cytotoxic CD8 <sup>+</sup> T cells expressing identical endogenous TCRA chains. <i>J. Immunol.</i> 157:4726.				
	Verdaguer, J., D. Schmidt, A. Amrani, B. Anderson, N. Averill, and P. Santamaria. 1997. Spontaneous autoimmune diabetes in monoclonal T cell nonobese diabetic mice. <i>J. Exp. Med.</i> 186:1663.				
	Vyse, T., and J. Todd. 1996. Genetic analysis of autoimmune disease. <i>Cell</i> 85:311.				
	Wang, B., A. Gonzalez, C. Benoist, and D. Mathis. 1996. The role of CD8 <sup>+</sup> T-cells in initiation of insulin-dependent diabetes mellitus. <i>Eur. J. Immunol.</i> 26:1762.				
	Wicker, L., E. Leiter, J. Todd, R. Renjilian, E. Peterson, P. Fischer, P. Podolin, M. Zijlstra, R. Jaenisch, and L. Peterson. 1994. b2-microglobulin-deficient NOD mice do not develop insulitis or diabetes. <i>Diabetes</i> 43:500.				
	Wong, F., I. Visintin, L. Wen, R. Flavell, and J. CA Janeway. 1996. CD8 T cell clones from young NOD islets can transfer rapid onset of diabetes in NOD mice in the absence of CD4 T cells. <i>J. Exp. Med.</i> 183:67.				
	Wong, S., et. al. 1999. Identification of an MHC class I-restricted autoantigen in type 1 diabetes by screening an organ-specific cDNA library. <i>Nature Med.</i> 5:1026.				
	Yagi, H., M. Matsumoto, K. Kunimoto, J. Kawaguchi, S. Makino, and M. Harada. 1992. Analysis of the roles of CD4 <sup>+</sup> and CD8 <sup>+</sup> T cells in autoimmune diabetes of NOD mice using transfer to NOD athymic nude mice. <i>Eur. J. Immunol.</i> 22:2387.				
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